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EXAMINER
LE, EMILY M

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/923,116	MCKAY, WILLIAM F.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/26/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19,42-49 and 51-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19, 42-49 and 51-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 65-72 are added. Claims 1-19, 42-49 and 51-72 are now pending and currently under examination.

Miscellaneous

2. The Examiner has noted that the current listing of the claims contains numerous spelling errors. For example, claim 11 recites "osteog nic", wherein it appears what is intended is "osteogenic".

Claim Rejections - 35 USC § 112

3. Claims 1-19, 42 and 56-59 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues that the recitation "at least" and "about" does not render the claims indefinite on the basis that "at least" is a commonly used expression, and long-accepted and controlling legal precedent clearly establishes that use of the term "about" does not render a claim indefinite--which is further evidenced by multitude of patents issued and continuing to issue using this claim term.

Applicant's arguments have been fully considered and found not persuasive. The indefinite rejection set forth in the previous rejection is based on the recitation of "at least about", not the sole use of "at least" or "about". The rejection is based on the use of the combination of "at least" and "about". The use of either "at least" or "about" is clear because the metes and bounds encompassed by such language is clear, therefore, are not rendered as indefinite. However, it is the combinational use of the

terms that renders the claims indefinite. It is unclear what the metes and bounds are for "at least about". It is unclear when the "at least" begins when it is combined with an "about", thereby rending the claims indefinite.

Claims 46-47 are also rendered indefinite. It is unclear what the dependency of claim 46. Currently, claim 46 recites a dependency to both claims 44 and 45. Claim 47 is indefinite because it depends on a claim that is rendered indefinite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 42-43, 45-48, 51-53 and 60-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Chu et al., U.S. Patent No. 4888366; wherein claims 42, 48, 51-53, and 61-62 remain rejected under 35 U.S.C. 102(b) as being anticipated by Chu et al.

Claim 42 is directed at an osteogenic composition comprising a carrier consisting essentially of a resorbable sponge matrix with particulate mineral embedded in said matrix, said mineral present in an amount constituting at least about 95% by weight of said carrier, and an osteogenic factor.

Claims 43, 45-47, 51-53 are directed at a sponge device consisting essentially of a resorbable sponge matrix formed of collagen and having particulate biocompatible mineral embedded within said matrix; said device comprised 1% to 3% by weight of the collagen and 97% to 99% by weight of the particulate biocompatible mineral. The

claims also further limit the mineral to include a synthetic ceramic. It is further interpreted by the Examiner that claim 46 depends on claim 45, therefore, the claims require that the ceramic to include calcium phosphate ceramic, which is later limited to biphasic calcium phosphate. The claims also limit the collagen to telopeptides.

The claims also further require that he composition comprise an osteogenic factor, wherein the factor comprises a bone morphogenic protein.

Claim 48 is directed at an osteogenic implant comprising a resorbable matrix carrier comprising 1% to 3% by weight of collagen in sponge form and 97% to 99% by weight of a particulate biocompatible mineral embedded within said collagen, and an osteogenic factor.

Claims 60-62 are directed to a sponge implant device comprising a resorbable sponge matrix, and a particulate biocompatible mineral embedded within said matrix, said device comprises 1% to 3% by weight of material forming said sponge matrix, and 97% to 99% by weight of the particulate biocompatible mineral. The claims also require that the device comprise an osteogenic factor. The claims limit the osteogenic factor to bone morphogenic protein.

Applicant argues Chu fails to anticipate claims 42, 48, 51-53 and 61-62 because neither the extreme ranges of high mineral content, 95%+ or 97%-99%, to low collagen content--1%-3%, their unexpected advantages, nor the problems they solve are taught by the broad ranges expressed in Chu. Applicant continues by asserting that the office action fails to set forth reasons why the claimed elements are taught in the applied references with sufficient specificity, nor are any such reasons apparent from the

references. In the instance of Chu et al., Applicant argues that the office action concludes, completely summarily, that the ranges taught by Chu et al. anticipates the claimed ranges. Applicant continues with "[n]o analysis is provided as to why these broad ranges taught by Chu [et al.] teach the narrowly claimed ranges with sufficient specificity. Nor is any account taken in the office action of the express teachings in the application supporting the unexpected results obtained with the Applicant[']s claimed sponge materials, or the problems that they solve." Applicant continues by pointing to the specification for evidence of the unexpected results obtained with the Applicant's claimed sponge materials, or the problems that they solve.

Applicant's argument has been fully considered, however, is found not persuasive because Chu et al. teaches ranges that are either within or overlapping with those that are instantly claimed. "[A] prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nontheless inherent in it." See In re Oelrich, 666 F.2d at 581. Additionally, the courts have determined that "[I]nherency is not necessarily coterminus with the knowledge of those of ordinary skill in the art." See Mehl/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999). That is, it need not have been appreciated or recognized that the prior art reference inherently discloses the same invention for the reference to be anticipatory. See Mehl/Biophile Int'l Corp. v. Milgraum 192 F.3d 1362, 1365 (Fed. Cir. 1999); Atlas Power Co. v. Ireco Inc., 190 F.3d 1342, 1347 (Fed. Cir. 1999).

Therefore, in view of the discussion above, Applicant's arguments are found not persuasive; ergo, the rejection stands.

The following is a discussion of the validity of Chu et al. in anticipating claims 42-43, 45-48, 51-53 and 60-62; wherein claims 42, 48, 51-53, and 61-62 remain rejected under 35 U.S.C. 102(b) as being anticipated by Chu et al.

Chu et al. teaches of osteogenic sponge compositions that comprises a resorbable sponge matrix material, an effective amount of osteogenic factor, and particulate mineral embedded in said matrix.

The osteogenic sponge compositions taught by Chu et al. comprises 60-98%, preferably 75-98% by weight of particulate mineral to 2-40%, preferably 5-25% by weight of resorbable sponge matrix material. The percentages given by Chu et al. anticipates the "mineral present in an amount constituting at least about 95% by weight of said carrier" and "1% to 3% by weight of the collagen and 97% to 99% by weight of the particulate biocompatible mineral" limitations.

The particulate mineral taught by Chu et al. is includes a synthetic ceramic, specifically biocompatible mineral, particularly calcium phosphate ceramic, preferably hydroxyapatite (HA) and tricalcium phosphate or mixtures of both--biphasic calcium phosphate. Additionally, the osteogenic factor taught by Chu et al. includes bone morphogenic protein. Chu et al. also discusses the use of telopeptides.

Chu, therefore, anticipates the instantly claimed invention.

6. Claims 67-71 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chu et al., U.S. Patent No. 4888366.

The claims require that the claimed osteogenic composition be three-dimensionally stable but flexible.

Chu et al. anticipates the instantly osteogenic composition. Any characteristics describing the instant composition would be inherent features in the composition of Chu et al. because the instant composition and the composition of Chu et al. is indistinguishable.

7. Claims 43, 45-47 and 57-60 remain rejected under 35 U.S.C. 102(b) as being anticipated by Smestad et al., U.S. Patent No. 5123925.

In response to the above rejection, Applicant uses the same rejection as that used for Chu et al.: ...fails to anticipate ...because neither the extreme ranges of high mineral content... to low collagen content--their unexpected advantages, nor the problems they solve are taught by the broad ranges expressed.... Applicant continues by asserting that the office action fails to set forth reasons why the claimed elements are taught in the applied references with sufficient specificity, nor are any such reasons apparent from the references.

Applicant's argument has been fully considered, however, is found not persuasive because Smedstad et al. teaches ranges that are either within or overlapping with those that are instantly claimed. "[A] prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nontheless inherent in it." See In re Oelrich, 666 F.2d at 581. Additionally, the courts have determined that "[I]nherency is not necessarily coterminus with the knowledge of those of ordinary skill in the art." See Mehl/Biophile Int'l Corp. v. Milgraum, 192 F.3d

1362, 1365 (Fed. Cir. 1999). That is, it need not have been appreciated or recognized that the prior art reference inherently discloses the same invention for the reference to be anticipatory. See Mehl/Biophile Int'l Corp. v. Milgraum 192 F.3d 1362, 1365 (Fed. Cir. 1999); Atlas Power Co. v. Ireco Inc., 190 F.3d 1342, 1347 (Fed. Cir. 1999).

Therefore, in view of the discussion above, Applicant's arguments are found not persuasive; ergo, the rejection stands.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-8, 11-14, 18-19, 56-59 and 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4888366.

Claims 1-8 and 11-14 are directed to an osteogenic composition that comprises a resorbable sponge matrix material; an osteogenic factor, said osteogenic factor incorporated in said sponge matrix in an amount that causes an increased rate of resorption of said sponge matrix in a mammal; and a particulate mineral having an average particle diameter of at least about .5 mm embedded in said resorbable sponge matrix material, said mineral present in a weight ratio of at least 4:1 relative to said sponge matrix, so as to provide a scaffold for bone in-growth in the presence of said osteogenic factor. The weight ratio is further limited to 10:1. The claims limit the osteogenic factor to bone morphogenetic protein. The claims limit the matrix material to

include collagen. The claims limit the mineral to be selected from a group consisting of bone particles and biocompatible synthetic calcium phosphate ceramics. The claims further limit the mineral to biphasic calcium phosphate. The claims additional requires that the porosity of the biphasic calcium phosphate to be of at least about 50%. The claims also require that the osteogenic composition comprised at least about 95% by weight of said particulate mineral. The claims further limits the mineral diameter size to about .5 mm to about 5.0 mm, about 1 to about 2 mm. Additionally, the claims further limits the osteogenic factor to bone morphogenic protein.

Claim 18-19 are directed to an osteogenic sponge composition comprising a resorbable sponge matrix material; an osteogenic factor that stimulates osteoblasts and osteoclasts, said osteogenic factor incorporated in said sponge matrix material in an amount that causes an increased rate of resorption of said matrix material in a primate; and particulate mineral having an average particle diameter of at least about .5 mm embedded in said resorbable sponge matrix material, said mineral present in a weight ratio of at least 4:1 relative to said sponge matrix, so as to provide a scaffold for a duration sufficient for osteoid in-growth through an area in which said sponge composition is implanted. Claim 19 further limits the primate to a human.

Claims 56-59, which depends on claim 51, which depends on independent claim 43, requires that the mineral diameter size to about .5 mm, .5 mm to about 5.0 mm, and about 1 to about 3 mm.

The relevance of Chu et al. is discussed above. Chu also teaches collagen, specifically the atelopeptide forms-- fibrillar or non-fibrillar collagen components as the resorbable sponge matrix material.

The osteogenic composition of Chu et al. comprises an effective amount of osteogenic factor that causes an increased rate of resorption of said sponge matrix in a mammal; wherein the mineral and matrix components provides a scaffold for bone in-growth in the presence of said osteogenic factor.

Chu et al. does not teach the average particle diameter of the particulate mineral that is required as part of the claimed invention. Additionally, Chu et al. does not teach of 50% porosity for the biphasic calcium phosphate. However, Chu et al. teaches that the particulate mineral can be made from a number of mesh sizes and porosities. It would have been obvious for one of ordinary skill in the art at the time the invention was made to experiment with the different particle size and porosities as part of routine experimentation. One of ordinary skill in the art at the time the invention was made would have be motivated to do so to produce an optimal osteogenic composition for each instance of intended use of the osteogenic composition. One of ordinary skill in the art would have had a reasonable expectation of success because Chu et al. teaches how to make osteogenic compositions and clearly indicate that the particulate mineral can be made from a number of mesh sizes and porosities.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

Although Chu et al. does not teach the use intended use of the osteogenic composition in a primate. However, it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the osteogenic composition of Chu et al. in primates to repair bone defects and fractures. One of ordinary skill in the art at the time of the claimed invention would have been motivated to do so to repair bone defects and fractures.

One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success doing so because the composition of Chu et al. encourage bone formation.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

The instantly claimed invention is obvious over Chu et al. Any characteristics describing the instant composition would be inherent features in the composition of Chu et al. because the instant composition and the composition of Chu et al. is indistinguishable.

10. Claims 15-16, 54-55, 63-64 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4888366 in view of Parsons et al., U.S. Patent No. 5106626.

The claims further limit the bone morphogenic protein to BMP-2.

The relevance of Chu et al. is discussed above. Chu et al. does not teach the use of BMP-2, however, as mentioned above Chu et al. does teach the use of bone

morphogenic protein. Parsons et al. teaches an extensive listing of bone morphogenic proteins, including BMP-2 and recombinant human bone morphogenic protein.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to experiment with different types of bone morphogenic proteins as part of routine experimentation. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to arrive at an optimal osteogenic composition for the induction of bone growth.

One of ordinary skill in the art would have had a reasonable expectation of success for doing so because Chu et al. teaches an osteogenic composition that comprises bone morphogenic protein and Parsons et al. teaches an extensive listing of bone morphogenic proteins.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4888366 in view of Ducheyne et al., U.S. Patent No. 5874109.

The claim additionally requires the presence of transforming growth factor-beta.

The relevance of Chu et al. is discussed above. Chu et al. does not teach the addition of transforming growth factor-beta. However, Ducheyne et al. teaches that BMP-2 through 7 are all members of the TGF-.beta. superfamily.

MPEP § 2144.06 recites the conclusions of *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA), "It is prima facie obvious to combine two compositions

each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose...[T]he idea of combining them flows logically from their having been individually taught in the prior art." Therefore, since the instantly claimed invention is drawn to combining known ingredients, the combination of their additive effects renders the invention prima facie obvious and does not exhibit an unexpected result. Therefore, one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for producing the claimed invention, absent of unexpected results to the contrary.

12. Claims 9-10 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4888366 in view of Urist, U.S. Patent No. 4795804.

The claim additionally requires the particulate mineral include bone particles, which is further limited to cortical bone particles.

The relevance of Chu et al. is discussed above. Chu et al. does not teach the inclusion of bone particles. However, Urist teaches of bone particles, which is further limited to cortical bone particles. Urist teaches the extraction of human bone morphogenic protein from the cortical bone particles.

One of ordinary in the art at the time the invention was made would have been motivated to use the cortical bone particles of Urist in the composition of Chu et al. because cortical bone particles is a natural product and that it bone growth factor(s).

One of ordinary skill in the art would have had a reasonable expectation of success for doing so because both references teach osteogenic compositions for bone growth/repair.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

13. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4888366 in view of Michelson, U.S. Patent No. 5785710.

The claim is directed to an interbody spinal fusion device comprising a load bearing member sized for insertion between adjacent vertebrate and a composition according to any of claims 1-49 and 42-48 retained by said member.

The relevance of Chu et al. is discussed above. Chu et al. does not teach an interbody spinal fusion device comprising a load bearing member sized for insertion between adjacent vertebrate. However, Michelson teaches an interbody spinal fusion device comprising a load bearing member sized for insertion between adjacent vertebrate.

One of ordinary in the art at the time the invention was made would have been motivated to do so to use the interbody spinal fusion device of Michelson for the delivery of the composition of Chu et al.

One of ordinary skill in the art would have had a reasonable expectation of success for doing so because Chu et al. teaches an osteogenic composition and Michelson teaches an interbody spinal fusion device.

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E.Le

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